K133672

SECTION 5: 510(k) SUMMARY

Submitter:
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Contact:
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Date of preparation: 27 November 2013

Name of device: *Trade/Proprietary Name:* Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology
Classification Name: Scalpel, Ultrasonic, Reprocessed, General & Plastic Surgery
Classification: Unclassified
Product Code: NLQ

Model Numbers	Primary Predicate	Secondary Predicate(s)
HAR36 HAR23	**K120729** *HARMONIC ACE® Shears + Adaptive Tissue Technology* (Ethicon-Endo Surgery, Inc.)	**K060245** *Harmonic Scalpel Blades and Shears, Models ACE36E and ACE23E* (Ethicon-Endo Surgery, Inc.)

Device Description:

Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology are sterile, single patient use instruments consisting of an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level and MAX for maximum power level).

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The instruments have a clamp arm and coated curved blade that are designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The instrument shafts can be rotated 360° to facilitate visualization and access to targeted tissue. The instruments allow for the coagulation of vessels up to and including 5 mm in diameter.

Each instrument is shipped with one sterile, single-use, disposable torque wrench.

HARMONIC ACE® Shears without Adaptive Tissue Technology are designed for use exclusively with the Generator G11 (GEN 11) software version X or later. The scope of this Traditional 510(k) only includes the reprocessed Ethicon Harmonic Shears and not the generator.

Indications for Use:
Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.

Technological Characteristics:
The reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology incorporate most of the same technological characteristics as that of the predicate device. The mechanism of action of Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology are identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. The only difference is that the reprocessed devices do not contain the adaptive tissue technology as marketed by the original manufacturer. In addition, Stryker Sustainability Solutions' reprocessing of HARMONIC ACE® Shears without Adaptive Tissue Technology includes removal of adherent visible soil and decontamination after original device use. Each individual HARMONIC ACE® Shears without Adaptive Tissue Technology is tested for appropriate function of its components prior to packaging and labeling operations

Performance data:
Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology perform as originally intended for cutting and coagulating soft tissue and sealing vessels up to 5mm in diameter.

Conclusion:
Stryker Sustainability Solutions concludes that the reprocessed devices are as safe and effective as the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

Stryker Sustainability Solutions
Mr. Scott English
Regulatory Affairs Specialist
1810 West Drake Drive
Tempe, Arizona 85283

Re: K133672
Trade/Device Name: Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology
Regulatory Class: Unclassified
Product Code: NLQ
Dated: March 31, 2014
Received: April 3, 2014

Dear Mr. English:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Model Number	Device Description	Diameter	Length
HAR23	Reprocessed Harmonic ACE Shears without Adaptive Tissue Technology	5 mm	23 cm
HAR36	Reprocessed Harmonic ACE Shears without Adaptive Tissue Technology	5 mm	36 cm

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133672

Device Name: Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology

Indications For Use: Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S